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Johanna Henrica Gerdina Maria Mutsaers

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

01/27/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOMAIL@nixonvan.com
clm@nixonvan.com

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/584,921 | Applicant(s) MUTSAERS ET AL. | |
| | Examiner HOPE ROBINSON | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-3,5-9,11,12 and 15 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-3,5-9,11,12 and 15 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☒ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Application Status

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1652.
2. Applicant's response to the Office Action mailed July 5, 2011 on October 31, 2011 is acknowledged.

Claim Disposition

3. Claims 4, 10, 13 and 14 have been canceled. Claims 1-3, 5-9, 11-12 and 15 are pending and are under examination.

Claim Objection

4. Claims 1-3, 5-9 and 11-12 are objected to because of the following informalities:

For clarity and precision of claim language it is suggested that claim 1 is amended to read, "A process for the production of a food product from whey, wherein said whey contains annatto as a pigment, the process comprising: contacting whey comprising annatto pigment with...".

For clarity it is suggested that claims 2-3 and 5-7 are amended to read, "The process of claim X₁ wherein,".

For clarity and precision of claim language it is suggested that claim 5 is amended to read, "...produced in situ by a microorganism that produces said enzyme", in lieu of "capable of".

For clarity and consistency it is suggested that claims 5 and 6 are amended to read, "obtained from" in lieu of "derived from".

For clarity claim 8 should be amended to read, "A food product made by the process of claim 1" (see also claim 9 with similar language).

For clarity it is suggested that claims 11 and 12 are amended to read, "The process of claim X...".

Appropriate correction is required.

Maintained and Amended-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 - 3, 5-9, 11-12 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a process for the production of a food product from a whey containing annatto as a pigment wherein said process comprises contacting the aforementioned whey with at least one enzyme for which annatto is a substrate under conditions such that at least a portion of the annatto present in the whey is converted directly by said at least one enzyme to whiten said whey and preparing the food product from the whitened whey. The claimed invention is not adequately described because the process encompasses a large variable genus of enzymes which are to directly convert a portion of the annatto pigment present in the whey. The process does steps do not establish what enzyme is used or what annatto substrate. In addition, the objective of the instant method is "production of a food product" and there are no direct steps in the method leading to same. It is noted that step (a) accomplishes bleaching a portion of the annatto pigment present in whey and that step (b) is directed to preparing the food product from the whitened whey, however, there is no indicia as to

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what food product or what preparation steps are necessary to achieve said food product. Thus it does not appear that the steps present in the process are sufficient to achieve the recited objective in the preamble of the claim.

The claimed invention does not set forth in for example claim 1 whether the whey is liquid or a dried form, such as whey flour. It is noted that claim 2 recites, that the food product is made from flour, however the process of claim 1 does not indicate whether the whey is processed into cheese or a whey flour, and there a no process steps to lead to either product. The claimed invention also sets forth that the enzyme involved in the process is added as an enzyme preparation derived from a microorganism or produced in situ by a microorganism capable of producing said enzyme, however, no specific enzyme is provided to be able to determine what microorganism is utilized in the process. It is further stated that the microorganism is a bacterium, fungus or yeast, however, again no specific one is provided. The claims point to the fungus *Marasmius scorodonius* however, no specific enzyme is provided. No steps are provided in the process to achieve the recited "wheat flour". In addition, no specific beta carotene converting enzyme is provided in the claimed process for whitening. Thus, the claimed invention is not adequately described.

The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative

number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Moreover, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of enzymes for example, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993).

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Maintained and Amended-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 - 3, 5 - 9, 11, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brody et al. US 6,120,820 in view of Zorn, (Applied Microbiology and Biotechnology 62:331-336, 2003) further in view of US Dairy Export Council, 1999; Davisco Foods International, 2003; and FASonline, 2003.

Brody et al. discloses a process for the production of a food product (reduced color whey product) (col. 11, paragraph 4) which comprises contacting a whey intermediate containing annatto as a pigment with at least one bleaching agent for which annatto is a substrate under conditions such that at least a portion of the annatto present in the whey intermediate is converted to a form a whitened whey intermediate. Brody et al. further discloses that any suitable bleaching material would be used (col. 11, paragraph 2), which reads on claims 1 - 3 and 15. However, claim 1 differs from Brody et al. in specifying the use of an enzyme which is a direct conversion enzyme. In-so-far-as Brody et al. do not expressly teach an enzyme; Zorn discloses the bleaching of carotenoids, beta-carotene, and (degradation) can be accomplished by the use of fungal enzymes. In order to determine which fungal source enzymes would provide optimal bleaching activity (degradation) in carotenoids such as beta-carotene, Zorn measured said activity by a conventional photometric bleaching test in which the enzymatic activities were measured by the amount of bleaching

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(degradation) occurring in beta-carotene. Zorn therefore discloses that it is conventional and known in the art that carotenoids are bleached by fungal based enzymes. *M. scorodoni* in particular was characterized by Zorn as having a high activity with respect to the degradation of beta- carotene (see abstract, page 333, col. 2, paragraph 3, table 1 and page 334, col. 1, bottom of the page, table 2 of the Zorn reference). While Zorn is cleaving beta-carotene, a carotenoid, to derive flavor compounds Zorn discloses that it is known in the art that the bleaching of carotenoids can be accomplished using fungal based enzymes, which is also applicant's intended reason for the use of such enzymes. As it is known that a particular enzyme can bleach carotenoids the substitution of one conventional method known to bleach carotenoids for another conventional method, such as the enzyme shown by Zorn to bleach carotenoids is seen to have been an obvious matter of choice and/or an obvious result effective variable, particularly if higher activities were known to be present in one variety over another as is seen in table 2 of Zorn. To therefore modify the teachings of Brody et al. and use a direct converting enzyme to bleach a food product would have been an obvious matter of choice and/or an optimization of expected results. An express suggestion to substitute one equivalent component for another is not necessary to render such substitution obvious (MPEP 2144.06 II.). Further given that it is well established that beta-carotene can be bleached by fungal based enzymes, in particular *M. scorodoni*, and that beta-carotene and the active coloring compound of annatto are both carotenoids it would have been obvious to try to bleach an annatto containing

whey based on the teachings of Zorn, that is, to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success.

Further, Brody et al. prepared a food product from the whitened whey product obtained in step (a), spray dried product. In addition, as evidenced by US Dairy Export Council, Davisco Foods International, and FASonline, it was conventional and well established to use whey to prepare flour and/or dairy based food products. To therefore, have used the whey of Brody et al. in view of Zorn to prepare flour based or a dairy based food product would have been an obvious matter of choice and/or an obvious result effective variable. Regarding claims 5, 6, 7, and 12, Brody et al. in view of Zorn further in view of US Dairy Export Council, Davisco Foods International, and FASonline discloses the enzyme is added as an enzyme preparation derived from a microorganism or produced in situ by a microorganism, that is, in particular, *Marasmius scorodoni* (Zorn; abstract) which is a fungus (Zorn; page 331, paragraph 3).

Regarding claims 8 and 9, Brody et al. in view of Zorn further in view of US Dairy Export Council, Davisco Foods International, and FASonline discloses a method of making a food product by the process according to claim 1 (bread) ('336; title) it is expected that the product would have been made by the process as claimed. Further Brody et al. in view of Zorn further in view of US Dairy Export Council, Davisco Foods International, and FASonline discloses that at least one part of the food product has been subjected to treatment with an enzyme according to the process of claim 1 (whey product). Regarding claim 11, absent evidence of criticality it is not seen that patentability would be predicated on the use of wheat flour since it is notoriously old and

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established to provide food products prepared from wheat flour. In any case Brody et al. in view of Zorn further in view of US Dairy Export Council, Davisco Foods International, and FASonline disclose the use of wheat flour to prepare food products was conventional (US Dairy Export Council, page 4, col. 2).

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole, a process for producing a food product from whey containing annatto because the combined teaching of the references renders the aforementioned process as obvious. To therefore modify the teachings of Brody et al. and use a direct converting enzyme to bleach a food product would have been an obvious matter of choice and/or an optimization of expected results. Moreover, the Supreme Court pointed out in *KSR*, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 127 S. Ct. at 1741. The Court thus reasoned that the analysis under 35 U.S.C. 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the “inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 1741. The Court further advised that “[a] person of ordinary skill is...a person of ordinary creativity, not an automation.” *Id.* at 1742. Therefore, the claimed invention was obvious to make and use at the time the invention was made and was *prima facie* obvious.

Response to Arguments

8. Applicant's comments have been considered in full. Withdrawn objections/rejections will not be discussed herein as applicant's comments are moot. Note that a rejection remains under 35 USC 112, first paragraph, however, has been revised to address issues inadvertently missed by the previous examiner. Applicant's comments regarding the new matter rejection were carefully considered and that aspect of the rejection is withdrawn.

Applicant's comments regarding the Brody et al. reference was on point with regard to the enzyme, however, applicant discusses the reference individually and the combined teaching of the references, renders the claimed invention as obvious. Further, applicant indicates that the process in the art utilizes heat, however, the claimed process has the open language of "comprising", and hence additional steps can be present in the art. Thus applicant's comments are not persuasive and the rejection remains. Note that amendments have been made to the rejection for purposes of clarification.

Conclusion

9. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652